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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/402,450	09/01/89	MURAKAWA	G

HM12/0214

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EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1631	42

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
07/402,450	Murakawa et al.
Examiner	**Group Art Unit**
Ardin Marschel	1631

☒ Responsive to communication(s) filed on *Nov 28, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *34-49* is/are pending in the applicat

[redacted], Claim(s) *1-33 have been canceled.* [redacted]

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *34-49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments, filed 11/28/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 34-41 and 46-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instantly pending claims contain NEW MATTER due to being broader in scope than the disclosure as filed. The instant invention is described in the SUMMARY OF THE INVENTION section as being directed to the determination of the presence or absence of "viral" RNA. No other target RNA or target DNA has been instantly disclosed. It is noted that viral DNA amplification within the instant method is an embodiment thereof as disclosed in application Serial Number 07/143,045 on page 8, lines 15-18, which has been incorporated by reference into the instant application. Thus, the instant claims which are generically broad in citing target nucleic acid contains NEW MATTER as being directed to target nucleic acid which is deemed to include non-

viral RNA or DNA. This broader scope is NEW MATTER. This rejection is maintained and reiterated from the previous office action because the claims have not been limited to "viral" detection practice.

Claim 49 is rejected under 35 U.S.C. § 135(b) over Wang et al. (P/N 5,219,727).

This rejection is reiterated and maintained from the previous office action, mailed 8/30/00. Applicants are firstly reminded that this rejection is based on 35 U.S.C. § 135(b) and not 35 U.S.C. § 102(b) as noted in their arguments. It is additionally noted that instant claim 49 has not been amended to be limited to "viral" target practice. Thus, the basis for this rejection still applies. Applicants have argued that they have amended to limit claim 49 to subject matter for which there is priority that predates the Wang et al.(P/N 5,219,727). This is non-persuasive due to the remaining breadth of claim 49 and that the issue under 35 U.S.C. § 135(b) is not priority of disclosure but that a claim was not submitted for examination in the instant application prosecution history before the one year had elapsed after the issuance date of the reference. Therefore, the arguments of applicants are non-persuasive in overcoming this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under

this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 37, 41, and 48 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Mullis et al.(P/N 4,683,195).

This rejection is reiterated and maintained, and as necessitated by amendment as discussed below, from the previous office action, mailed 8/30/00, except that the instant kit claims 36 and 40 have been withdrawn as being rejected hereinunder due to the persuasive argument regarding said kit claims. Applicants argue that the target RNA sequence amplification limitation of the instant claims are not the DNA sequences of the reference. In response the instantly rejected claims are product claims wherein the process of target RNA amplification is part of a process for defining the claimed products. None of instant claims 37, 41, or 48 are directed to methods. This being the case, the target sequences may be considered as sequences per se with their origins being RNA but now DNA as utilized in the PCR

reactions of the reference. It is well known that the DNA sequence of the target sequences in the plasmids utilized in the reference is the same as either RNA or DNA of that segment of the hemoglobin gene or mRNA. Thus, the capability to perform amplification in a PCR procedure is identical whether a RT-PCR type of reaction is utilized to make DNA to be amplified from a hemoglobin mRNA segment or whether the DNA is a segment obtained from a cDNA molecule that was made double-stranded after reverse transcription from mRNA. Thus, the plasmid per se would equally serve as an internal control whether RNA was the initial target material of a DNA with hemoglobin cDNA sequence that was prepared from mRNA. Thus, the claimed control plasmids are products by process which are not limited per se to a method wherein RNA target is initially amplified by are equally usable wherein DNA is that target. It is additionally noted that the target RNA in the instant claims 37, 41, and 48 are not limited to "viral" RNA target and therefore the hemoglobin sequence target of the reference still falls within the sequence process limitations of the rejected claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 36 and 40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mullis et al.(P/N 4,683,195); taken in view of the kit description in the 1988 Stratagene Catalog.

This rejection is reiterated and maintained, and as necessitated by amendment as discussed below, from the previous office action, mailed 8/30/00. Applicants firstly argue that there is no motivation to quantitate target sequence following amplification. This is non-persuasive in that the presence or absence of amplified target sequence was discussed in the previous basis for this rejection. This presence or absence evaluation is deemed a quantitation and is motivated and suggested as one of the results discussed as significant in the

reference. Applicants then argue that the Stratagene Catalog does not suggest quantitation or PCR practice as being the basis for kit practice. In response, the Catalog reference was not cited for either PCR per se or quantitation per se but rather for the description therein that the assembly of the desired biochemicals into kit form for at least the availability that such kits provide for Biochemical reactions. Thus, applicants' argument is not directed to the basis for the rejection which is the combination of references and not the Stratagene Catalog description alone.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 35-37, 39-41, and 43-45 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 32-34, 36-38, and 40-42 of copending application Serial No. 08/769,584. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented. This rejection is reiterated and maintained from the previous office action, mailed 8/30/00, as the actual reaction mixtures, kits, and plasmids of the respective claims are identical even though the targets are defined either as RNA or generic nucleic acid. This product by process identity which is the same for these claims was also noted above regarding targets being RNA or identical DNA sequence still being processes that are practiced with the same reaction mixtures, kits, and plasmids. This discussion of the basis for this rejection is a response which is necessitated by amendment.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-42 of copending application Serial No. 08/769,584. Although the conflicting claims are not identical, they are not patentably distinct from each other because each respective sets of claims include common embodiments of reaction mixtures and plasmids which are control standards which are usable to form amplification products which are distinguishable by size. Given the process steps cited in the composition claims instant claim 49 is included as an obvious use therefore. This rejection is reiterated and maintained from the previous office action and necessitated by amendment regarding those claims which were amended to change their scope so as to now be reconsidered and rejected under provisional obviousness-type double-patenting where they previously were rejected as being duplicate claims and thus rejected under a 35 U.S.C. 101 double-patenting rejection.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Prior to further processing of the instant application regarding the Request for Interference, the above issues must be addressed.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 9, 2001

ARDIN H. MARSCHEL
PRIMARY EXAMINER

John J. Doll, Director
Technology Center 1600